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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,813	04/20/2001	Robert Henry	54195-5001	3042

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,813

Applicant(s)

HENRY ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 8/20/2002 has been entered.

Claims 22-42 are pending.

Claims 32-42 are withdrawn from consideration for being drawn to a non-elected invention.

Claims 22-25 have been amended.

Claims 22-31 are examined in this office action.

2. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

3. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/10/2002. Applicant's arguments filed 8/20/2002 have been fully considered but they are not persuasive.

Applicants have amended claim 31 to recite "plant DNA" instead of a "gene".

Applicants assert that they do not have to describe their invention *ipsis verbis* for purposes of written description (page 5, 2nd paragraph) but rather, what is important is that the skilled artisan understand the invention based on the disclosure as recited in the specification. Applicant asserts that the skilled artisan would have understood that the recipient cell was transformed with DNA

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directly isolated from a donor plant (page 6, 1st sentence). Applicants contend that the specification discloses recipient cells transformed with donor plant DNA and “nothing more is needed to satisfy the written description requirement” (page 6, end of 1st paragraph). Applicant’s conclude by stating the skilled artisan, armed with the teachings of the invention, would have understood that a recipient cell was transformed with DNA isolated from a donor plant and that the invention was not limited to “any specific gene, features inherent to the gene, or any phenotype of the recipient cell” (page 7, 1st paragraph).

The Examiner acknowledges that Applicant is claiming a recipient cell transformed with DNA isolated from a donor plant. Because of the broad claim language, Applicant is claiming any cell transformed with any DNA. The skilled artisan understands the process or method by which the cell was transformed, but the artisan cannot describe the genotype or phenotype of the claimed cells. The reason for this is because the Applicant has not described the particular piece of DNA that was used to transform the recipient cell. The Applicant has not disclosed identifying characteristics of the genetic material nor of the transformed recipient cell. Because Applicant has not described the DNA used to transform the recipient cell, and because the Applicant has not described the genotype or phenotype of the transformed recipient cell, the written description requirement is not satisfied and claim 31 remains rejected.

4. The rejection of claims 22-27 under 35 U.S.C. 102(b) as being anticipated by Hadi et al (1996 Plant Cell Reports 15:500-505) is withdrawn based on Applicant’s amendment.

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5. The rejection of claims 22-23, 26-28, and 30-31 under 35 U.S.C. 102(b) as being anticipated by Christou (1997 Plant Molecular Biology 35:197-203) is withdrawn based on Applicant's amendment.

6. The rejection of claims 22-31 under 35 U.S.C. 103(a) as being unpatentable over Christou (1997 Plant Molecular Biology 35:197-203) and Hadi et al (1996 Plant Cell Reports 15:500-505) taken with Weining et al (1991 Theor Appl Genet 82: 209-216) and further in view of Applicants' admitted state of the prior art is withdrawn based on Applicant's amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 31 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turbin et al (1975, Mutation Research 27:59-68).

The claim is broadly drawn to any plant cell containing any "directly isolated" donor DNA which has not been characterized and which is not contained in a vector. Turbin et al

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teach barley cells and tissues which contain uncharacterized DNA directly isolated from other barley plants, not contained in a vector. The plant cells and tissues taught by the prior art differ from the claimed cells and tissues only in their method of manufacture, i.e. microprojectile bombardment. However, the claimed method of making the cells and plants would not confer a unique property to the resultant plants which would distinguish them from the prior art plants. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

8. Claims 22-25, 27, 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said isolated DNA is not present in a vector and is high molecular weight DNA and a selection marker gene is present in a selection construct and wherein said donor plant and said recipient plant are members of different species or wherein both donor and recipient are cereal plants. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al teach a method of transforming a barley plant with directly isolated and uncharacterized genomic DNA isolated from another species of barley, which is a cereal plant

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and a plant produced by this method. The office interprets said DNA to be high molecular weight DNA because both processes of isolating DNA produce long molecules of DNA.

Turbin et al do not teach transforming a plant using microprojectile bombardment wherein the plant is a species of *Oryza sativa* and incorporating a selection marker gene in a construct.

Christou teaches a method of transforming *Oryza* using microprojectile bombardment and transforming a plant with a selection marker gene that is present in a selection construct (page 201, sentence bridging left and right columns).

It would have been within the scope of one of ordinary skill in the art to modify the method of Turbin et al and to use the microprojectile bombardment method as taught by Christou. The motivation is taught by Christou who states that microprojectile bombardment is “the best method for achieving truly genotype-independent transformation” (page 198, right column, 1st paragraph).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

9. Claims 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203) as applied to claims 22-25, 27, 28, 30-31 above, and further in view of Applicants' own admitted statement of the prior art (page 18, lines 17-18, Xiao et al 1996. Nature 384:223-) and Weining et al (1991 Theor. Appl. Genet. 82:209-216).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said isolated DNA is not present in a vector and is high molecular weight DNA and a selection marker gene is present in a selection construct and wherein said donor plant and said recipient plant are members of different species or different genera or wherein both donor and recipient are cereal plants and the donor plant is a species of *Zizania palustris*. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al in view of Christou teach a method of transforming a barley plant with directly isolated and uncharacterized high molecular weight genomic DNA isolated from another species of barley, which is a cereal plant and a plant produced by this method and a method of transforming *Oryza* using microprojectile bombardment and transforming a plant with a selection marker gene that is present in a selection construct.

Turbin et al in view of Christou do not teach a donor plant and recipient plant from different genera nor where the donor plant is of the species *Zizania palustris*.

Applicants' admitted statement of the prior art teaches wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield wherein *Zizania palustris* is a wild rice species.

Weining et al teach isolation of DNA from grasses and cereal plants.

Given the recognition of those of ordinary skill in the art of the value of producing a rice plant transformed with uncharacterized, high molecular DNA isolated from another species of rice plant and transformed by microprojectile bombardment as taught by Turbin et al in view of Christou, it would have been obvious to use the method of Turbin et al in view of Christou and to

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modify this method taught by Applicants' own admitted statement of the prior art by isolating DNA from the wild rice species, *Zizania palustris* as taught by Weining et al.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Stuart Baum Ph.D.

November 15, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600